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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,271	01/14/2005	Hadi Aslan	28921	4523
7590		10/17/2007		
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			EXAMINER	
			WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,271

Applicant(s)

ASLAN ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response to the restriction requirement received on 8/6/07 has been entered. Applicant's election of the invention of Group I and further the species of a) an unmodified mesenchymal stem cell and a) an antibody interacting with human CD105 are acknowledged. As applicant has not indicated that this election was made with traverse or provided any arguments traversing the grounds for restriction, applicant's election is considered an election without traverse. Claims 1-24 are pending in the instant application. Of these, claims 7, and 9-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/6/07. Claims 1-6 and 8 are therefore currently under examination. An action on the merits follows.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/20/05 has been considered by the examiner. An initialed and signed copy of the 1449 is attached to this action. Please note that the citation number 16, Keunmyoung et al., is missing the page numbers. The examiner has added the correct page numbers to this citation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Majumdar et al. (2000) J. Cell. Physiol., Vol. 185, 98-106. The applicant claims a method of obtaining an isolated, non-culture expanded mesenchymal stem cell, comprising the following steps: contacting a human cell population with antibody that binds to a surface molecule expressed on a mesenchymal stem cell within the human cell population to form a cell-antibody-complex, recovering said mesenchymal stem cell, and maintaining said recovered mesenchymal stem cell under conditions preventing significant cellular expansion, wherein the antibody interacts with human CD105. The applicant further claims said method wherein the human cell population comprises unfractionated bone marrow, wherein the antibody is supported on a column, plastic, array or magnetic bead, or wherein the recovered mesenchymal stem cells are capable of differentiating into bone, marrow stroma, or spleen tissue.

Majumdar et al. teaches the isolation of human bone marrow-derived multipotential stromal cells comprising the steps of obtaining human bone marrow and contacting the bone marrow cells with an anti-human CD105 antibody microbeads, isolating the antibody bound cells using a magnetic column, and recovering the human CD105+ cells by washing the column with elution buffer, thereby obtaining the multipotential stromal cells (Majumdar et al., page 99). Please note that Majumdar et al. further teaches that multipotential stromal cells comprise mesenchymal stem and progenitor cells, and that the cell surface expression profile of the

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CD105+ cells is similar to that of mesenchymal stem cells obtained by other methods (Majumdar et al., page 98, column 2, and page 105, column 1). Majumdar et al. also teaches using these isolated cells directly following their elution from the column in FACS assays without culture expansion (Majumdar et al., page 105, column 1).

In regards to the limitation “maintaining said recovered mesenchymal stem cell under conditions preventing significant cellular expansion”, the specification does not give any precise definition of how the cells are to be “maintained” or for what period of time the cells are to “maintained”. However, it is noted that the specification does teach on pages 6-7 that the conditions for avoiding cellular proliferation include culture conditions, time in culture, or environmental conditions, and specifically culture or use of the cells in less than 24 hours. As such, the direct use of the cells following elution from the magnetic column qualifies as maintaining the cells under conditions to prevent significant cellular expansion.

Regarding the multipotential properties of the human bone marrow derived CD105+ stromal cells, Majumdar et al. teaches that these cells were capable of differentiating into cells of the chondrogenic and hematopoietic lineages (Majumdar et al., page 105). While Majumdar et al. does not specifically demonstrate that these cells are further capable of differentiating into cells of the kidney, liver, or muscle, the ability to differentiate into multiple cell lineages is inherent to mesenchymal stem/progenitor cells. As such, the capacity to differentiate into cell types other than those in the chondrogenic and hematopoietic lineages is considered an inherent property of the CD105+ cells isolated by Majumdar et al.

Thus, by teaching the same methods steps as claimed, and by teaching the isolation of a CD105+ cell population using these methods steps which has the properties of mesenchymal

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stem cells, such as a similar a cell surface expression profile and ability to differentiate into multiple cell lineages, Majumdar et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633